



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/050,359	03/31/98	FOWLKES	D FOWLKES-4B

BROWDY AND NEIMARK
419 SEVENTH STREET N W
WASHINGTON DC 20004

HM22/0628

EXAMINER
MCCARTHY III, T

ART UNIT	PAPER NUMBER
1618	6

DATE MAILED: 06/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/050,359

Applicant(s)
Fowlkes et al.

Examiner
McCarthy, T.C.

Group Art Unit
1618



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-24 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-24 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

Keith D. MacMillan
KEITH D. MacMILLAN
PRIMARY EXAMINER

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1618

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, drawn to a process for identifying a ligand that can mediate the biological activity of a target protein, classified in class 435, subclass 7.1+.
 - II. Claim 20, drawn to use of inhibitory ligands for manufacture of a composition, classified in class 424, subclass 184.1+.
 - III. Claims 21-23, drawn to a structured panel of biased combinatorial peptide libraries, classified in class 530, subclass 300+.
 - IV. Claim 24, drawn to a biased combinatorial peptide library, classified in class 530, subclass 300+.

Note: for the purposes of examination, the terms method and process are assumed to be equivalent.

2. The inventions are distinct, each from the other because of the following reasons:

3. Invention I draws to a process for identifying a ligand that can mediate the biological activity of a target protein, whereas invention II draws to the use of an inhibitory ligand for the manufacture of a composition that can mediate the biological activity of a target protein.

Invention I describes a process whereas invention II describes the use of a product (the ligands identified by the process of invention I) and are therefore distinct. Furthermore, the manufacture

Art Unit: 1618

of a composition that can mediate the biological activity of a target protein (invention II) can be accomplished using many different means (e.g. ligands other than those identified by the process of invention I, or synthetic compositions derived via classical methods of serial synthesis followed by hand testing).

4. Invention I draws to a process for identifying a ligand that can mediate the biological activity of a target protein, whereas invention III is drawn to a panel of biased combinatorial peptide libraries. The panel of combinatorial peptide libraries described by invention III can be used for purposes other than the one outlined by invention I (e.g. the peptides of invention III can be used as initiating moieties through which longer peptides can be synthesized). Furthermore, the process as described by invention I (to identify a ligand which can mediate the biological activity of a target protein) can be practiced by hand, testing one ligand at a time - without the benefit of a panel of combinatorial libraries. Therefore, inventions I and III are patentably distinct.

5. Invention I draws to a process for identifying a ligand that can mediate the biological activity of a target protein, whereas invention IV is drawn to a biased combinatorial peptide library. The combinatorial peptide library described by invention IV can be used for purposes other than the one outlined by invention I (e.g. the peptides of invention IV can be used as initiating moieties through which longer peptides can be synthesized). Furthermore, the process as described by invention I (to identify a ligand which can mediate the biological activity of a

Art Unit: 1618

target protein) can be practiced by hand, testing one ligand at a time - without the benefit of a combinatorial library. Therefore, inventions I and IV are patentably distinct.

6. Invention II draws to the use of an individual ligand, whereas invention III draws to a structured panel of biased combinatorial peptide libraries. A library is, by definition, two or more. Therefore, inventions II and III are patentably distinct.

7. Invention II draws to the use of an individual ligand, whereas invention IV draws to a biased combinatorial peptide library. A library is, by definition, two or more. Therefore, inventions II and IV are patentably distinct.

8. Invention III draws to a structured panel of biased combinatorial peptide libraries, whereas invention IV draws to a biased combinatorial peptide library. A panel of libraries is comprised of at least two libraries and is therefore different from a single library. Further, the structure of peptides comprised by the two inventions are different. Therefore, inventions III and IV are patentably distinct.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. However, some of the above distinct inventions fall within the same class and subclass. In these cases, restriction is also proper because of the reasons listed above, and because these inventions have acquired a separate status in the art due to their recognized divergent subject matter.

Art Unit: 1618

10. Should the applicant elect invention I, the following species elections will apply:

- A. A first library of peptides and/or peptoids (claims 2, 4, and 9),
- B. A first library of nucleic acids (claims 3 and 4),

Species A refers to a first library of either peptides or peptoids, or a composite library of the two. Species B refers to a first library of nucleic acids. Peptides and peptoids differ in structure, methods of synthesis, and function. Therefore, species A and B draw to patentably distinct species, and the applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

11. Invention I further contains claims directed to the following patentably distinct species of the claimed invention:

- A. A target protein that is an enzyme (claims 11-16),
- B. A target protein that is a transmembrane receptor (claim 17),
- C. A target protein that is a nuclear receptor (claim 18),
- D. A target protein that is an estrogen receptor (claim 19).

All of these proteins have different structures and functions. Therefore, the applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Art Unit: 1618

12. Should the applicant elect species A in paragraph 11 (above), the following species elections will also apply:

- A. A target protein that is associated with the human cytomegalovirus (claims 11 and 12)
- B. A target protein that is a protein kinase (claim 14),
- C. A target protein that is a tRNA synthetase (claim 15),
- D. A target protein that is a beta glucosidase (claim 16),
- E. A target protein that is a carboxypeptidase (claim 16),
- F. A target protein that is an alcohol dehydrogenase (claim 16).

The functions and structures of these enzymes are different. Therefore, the applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1618

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. A telephone call was made to Iver P. Cooper on June 21, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T.C. McCarthy whose telephone number is (703) 308-5316. The examiner can normally be reached on Monday to Friday from 8:00 am to 4:30 pm.


Application/Control Number: 09/050359

8

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Adams, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


KEITH D. MacMILLAN
PRIMARY EXAMINER

T.C. McCarthy III, Ph.D.

June 25, 1999